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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,612	01/24/2002	David W. Pipes	1670-233	6158

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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,612

Applicant(s)

PIPES ET AL.

Examiner

Mary (Molly) E. Ceperley

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 20, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-32 is/are pending in the application.
- 4a) Of the above claim(s) 18-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/07/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1641

1) The Alberto et al reference (AE) of form PTO-1449 is present neither in the file of the instant application nor in the file of the parent application and therefore has not been considered by the examiner.

2) Applicant's election without traverse of claims 27-32 in the response of January 20, 2004 is acknowledged. Claims 18-~~31~~³⁶ are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3) Although specific claims may be cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 27-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) In claim 27, the word "including" renders the claim indefinite as to its exact scope since it cannot be determined what other components might be "included" in the "kit" in addition to the "stannous ion" and "metal".

b) In claim 27, the term "may be" renders the claim indefinite since it is unclear as to what other form the "stannous ion" "may be" present in addition to the "discrete molecule" form. The "may be" language indicates that there is no requirement that the "stannous ion" be present in a "discrete molecule".

Art Unit: 1641

c) In claim 27, it is unclear what is meant by the term "discrete molecule".

d) Claim 27 is indefinite for the reason that it is unclear whether "lyophilized formulation" contains the "metal M" as a component in addition to the "stannous ion" or whether the "lyophilized formulation" is limited to the "stannous ion" *per se*.

e) In claim 30, it is unclear what is meant by the term "gluceptate" which does not appear to be a term well known in the art.

f) In claim 31, it is unclear exactly what is meant by the term "multidentate aminopolycarboxylate ligand".

6) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7) Claims 27-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description in the specification of the term "discrete molecule" used to further define the term "stannous ion" in claim 27. It is unclear what is meant by this term (see the 35 USC 112, second paragraph, rejection above).

8) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1641

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9) Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Azuma et al (U.S. 5,015,462) or Adler et al (U.S. 4,027,005).

Each of the references describes a kit comprised of lyophilized stannous ion in combination with radioactive technetium which anticipates the kit of claim 27. See Azuma et al, col. 4, lines 51-66; col. 3, lines 11-15; Example 2; Adler et al, col. 6, lines 24-29 and 37-48; claims 14-16; col. 8, lines 22-24.

10) Claim 30 is rejected under 35 USC 102(b) as being anticipated by Adler et al (U.S. 4,027,005)

Adler et al describe a kit comprised of lyophilized stannous ion, a salt of glucoheptonic acid ("gluceptate"), and radioactive technetium which anticipates the kit of claim 30. See col. 6, lines 24-29 and 37-48; claims 14-16 and **27**; col. 8, lines 22-24. The term "gluceptate" of instant claim 30 is the same as "a salt of glucoheptonic acid" of claim 27 of the reference.

11) Claims 31 and 32 are rejected under 35 USC 102(b) as being anticipated by Adler et al (U.S. 4,027,005).

Adler et al describe a kit comprised of lyophilized stannous ion, a salt of glucoheptonic acid ("gluceptate"), a multidentate ligand (DTPA), and radioactive technetium which anticipates the kits of claims 31 and 32. See col. 6, lines 24-29 and 37-48; claims 14-16 and 27; **col. 8, lines 14-24.**

12) Claims 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by MALLINCKRODT (WO 96/30054).

Art Unit: 1641

The reference describes a kit comprised of lyophilized stannous ion in combination with radioactive technetium and lactose as a pharmaceutically acceptable additive. This kit anticipates the kit of instant claims 27-29. See page 11, lines 8-30.

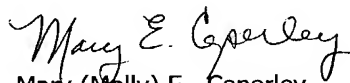
13) Note that the "for use in" limitation of the preamble of claim 27("for carrying out a method of preparing a compound of formula (II)") is not a limitation on the "**kit**" *per se*, i.e. any reference which describes the combination of "stannous ion" and "metal" in a kit useful for **any purpose** would anticipate the kit of instant claim 27.

14) An inquiry of a general nature which is **not related to the prosecution on the merits** should be directed to Technology Center 1600 telephone number (571) 272-1600. The general fax number for the USPTO is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823.

March 12, 2004


Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641